

Compliance Training for Retailers and Small Businesses

Compliance Information on the CTP
Website

April 10, 2012

Compliance Resources on the CTP Website

- Guidance documents
- Compliance Check Inspections of Tobacco Retailers
- Regulations
- Webinars and Notifying CTP about Potential Violations
- Other Resources on the CTP Website

Compliance Information on the CTP Website - Guidance

- A guidance document represents the Food and Drug Administration's (FDA) current thinking on a particular subject and provides information to assist in understanding and complying with relevant regulations and statutory requirements.
- Important way that FDA publicly communicates recommendations for how industry can comply with the law and regulations
- Ensures consistent advice to individual companies and other stakeholders
- Not legally binding

Compliance Information on the CTP Website - Guidance

- Draft Guidance
 - Typically issued before FDA publishes a final guidance to solicit comments from industry, other stakeholders, and the general public
 - An opportunity for all stakeholders to be part of the regulatory process
 - Amount of time for comments is specified however comments can be submitted at any time, even after Docket is closed

Compliance Education & Information - Guidance

- Comments are received from groups such as
 - Regulated industry
 - Researchers and Academics
 - Public Health
 - Other Federal government agencies
 - State, local and tribal governments
 - Individual citizens
- FDA will consider all comments before issuing a final guidance
- FDA's Division of Dockets Management is responsible for receiving and processing comments for all FDA dockets. Call (301) 827-6860 to verify receipt of your comments or go to <http://www.regulations.gov>.

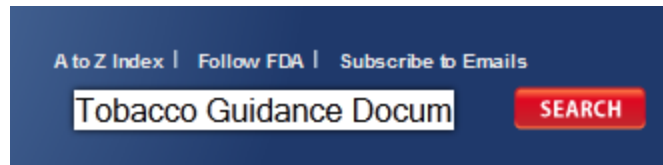
Compliance Information on the CTP Website - Guidance

Guidances applicable to retailers include:

- Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers
- General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2)
- Tobacco Retailer Training Programs
- Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents
- Copies of all guidances are found on our website

Compliance Information on the CTP Website - Guidance

- Type in “Tobacco Guidance Documents in the main search box.

A screenshot of the FDA CTP website's search bar. The search bar is a white input field with the text "Tobacco Guidance Docum" entered. To the right of the input field is a red button with the word "SEARCH" in white capital letters. Above the search bar, there are three links: "A to Z Index", "Follow FDA", and "Subscribe to Emails".

A to Z Index | Follow FDA | Subscribe to Emails

Tobacco Guidance Docum **SEARCH**

Guidance Documents

- [Required Warnings for Cigarette Packages and Advertisements - Small Entity Compliance Guide](#)
- [Draft Guidance for Industry Applications for Premarket Review of New Tobacco Products](#)
- [Draft Guidance for Industry Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products](#)
- [Draft Guidance for Industry and FDA Staff Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions](#)
- [Guidance for FDA and Tobacco Retailers Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers](#)
- [Draft Guidance for Industry: Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents \[Revision to Draft Guidance\]*](#)

Compliance Information on the CTP Website – Compliance Check Inspections of Tobacco Retailers

- FDA is authorized to contract with States, U.S. territories and Indian tribes to assist with compliance and enforcement activities to help limit the availability of tobacco products to youth.
- In FY 11, FDA contracted with 37 States and the District of Columbia.
- FDA conducts compliance check inspections of tobacco product retailers to determine a retailer's compliance with federal laws and regulations

Compliance Information on the CTP Website – Compliance Check Inspections of Tobacco Retailers

- FDA generally issues a Warning Letter the first time violations are observed during a compliance check inspection.
- A Warning Letter is the agency's advisory action that is used to achieve prompt voluntary compliance with the law.
- FDA generally issues Civil Money Penalty Complaints to tobacco retailers when subsequent violations are observed during a compliance check inspection.

Compliance Information on the CTP Website – Compliance Check Inspections of Tobacco Retailers

- FDA maintains a database that contains lists of inspected establishments where no violations were observed in states with FDA tobacco enforcement contracts.
- Also listed will be if the retailer received a Warning Letter and/or a Civil Money Penalty Complaint.
- The database contains links to view the Warning Letter or Civil Money Penalty Complaint as applicable.
- <http://go.usa.gov/UwP> (case sensitive)

Compliance Information on the CTP Website – Compliance Check Inspections of Tobacco Retailers

Compliance Check Inspections of Tobacco Product Retailers (through 02/29/2012)



[FDA Home](#) [Tobacco Products](#) [Information about Compliance Check Inspections](#)

Search Inspection Decisions [Help](#)

Retailer Name

Decision Type

City

Decision Date to

State

Zip

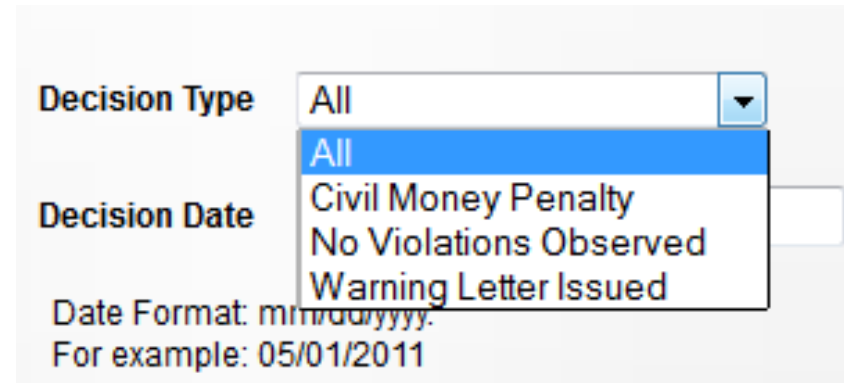
Date Format: mm/dd/yyyy.
For example: 05/01/2011

Records per Report Page

[Export All Data to Excel](#)

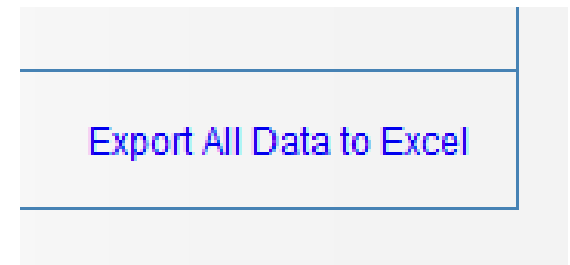
Compliance Information on the CTP Website – Compliance Check Inspections of Tobacco Retailers

- Search on Decision Type
- Combine with other search criteria. (date, city, state)
- Export to Excel the entire database
- Export the results of any individual search to Excel



The screenshot shows a search interface with the following elements:

- Decision Type:** A dropdown menu with a blue arrow icon. The menu is open, showing the following options: "All" (highlighted in blue), "Civil Money Penalty", "No Violations Observed", and "Warning Letter Issued".
- Decision Date:** A text input field.
- Date Format:** A label indicating the format "mm/dd/yyyy".
- Example:** A text label "For example: 05/01/2011".



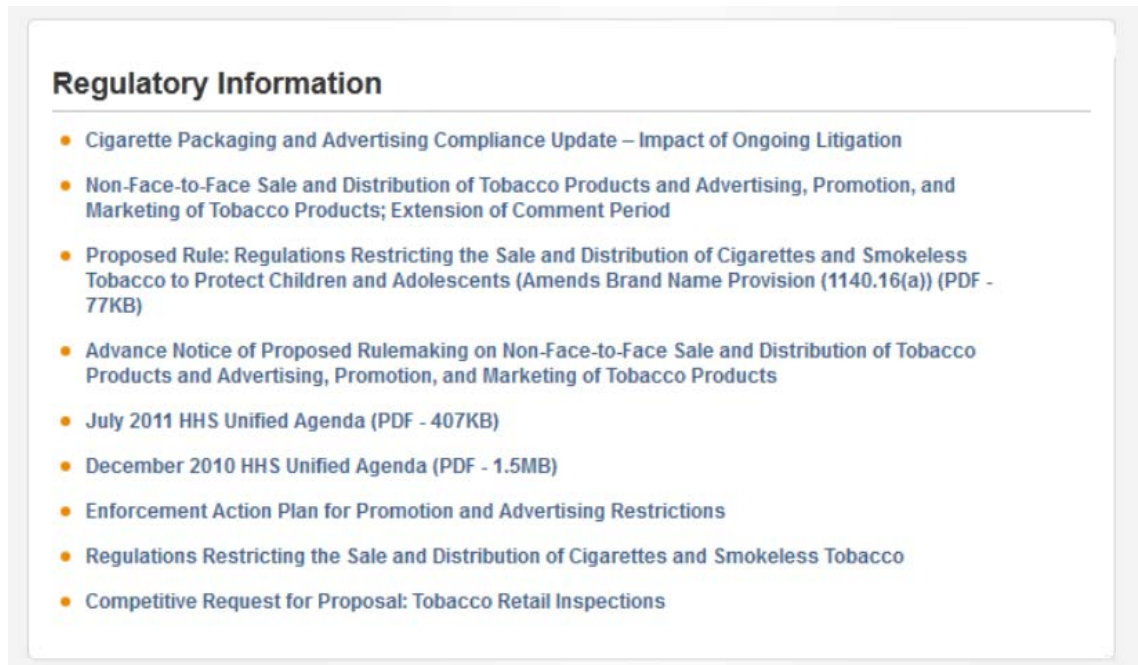
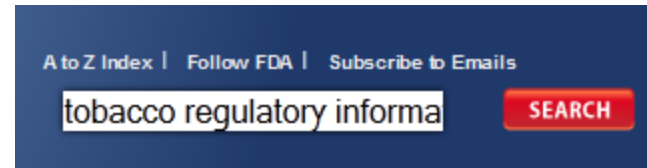
The screenshot shows a button with the text "Export All Data to Excel" in blue, centered within a light gray rectangular box.

Compliance Information on the CTP Website – Regulatory Information

- FDA enforces a set of laws and routinely issues regulations and guidance documents.
- The Federal Food, Drug, and Cosmetic Act (FD&C Act) is a federal law enacted by Congress. It and other federal laws (such as the Family Smoking Prevention and Tobacco Control Act) establish the legal framework within which FDA operates.
- FDA develops regulations based on the laws set forth in the FD&C Act or other laws under which FDA operates.

Compliance Information on the CTP Website – Regulatory Information


- Search in the main search box at top of page: Tobacco Regulatory Information.
- Of particular interest to retailers is the regulation restricting the sale and distribution of cigarettes and smokeless tobacco.



Compliance Information on the CTP Website – Webinars

[A to Z Index](#) | [Follow FDA](#) | [Subscribe to Emails](#)

SEARCH

 U.S. Department of Health & Human Services



U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

[A to Z Index](#) | [Follow FDA](#) | [Subscribe to Emails](#)

SEARCH

[Home](#) | [Food](#) | [Drugs](#) | [Medical Devices](#) | [Vaccines, Blood & Biologics](#) | [Animal & Veterinary](#) | [Cosmetics](#) | [Radiation-Emitting Products](#) | [Tobacco Products](#)

Tobacco Products

[Home](#) [Tobacco Products](#) [Resources for You \(Tobacco\)](#) [For Industry](#)

    [en Español](#)

Resources for You (Tobacco)

[For Industry](#)

[For Retailers](#)

[FDA Tobacco Compliance Webinars](#)

[2011 Archived Tobacco Compliance Training](#)

[2012 Archived Tobacco Compliance Training](#)

FDA Tobacco Compliance Webinars

FDA Center for Tobacco Products (CTP) is hosting a series of webinars on federal tobacco regulations. These webinars are designed to provide FDA tobacco compliance education and information to retailers and small businesses. Each webinar includes a Q&A session to provide participants the opportunity to have their questions answered by FDA.

[Sign up to receive email updates](#) about this webinar series.



Upcoming Dates

Archived Webinars

To listen to additional past retailer-focused webinars discussing the laws that restrict the sale, distribution and marketing of tobacco products, visit our archived pages.

- ♦ [2012 Archived Tobacco Retailer Compliance Trainings](#)
- ♦ [2011 Archived Tobacco Retailer Compliance Trainings](#)

Share your Ideas

We request your valued input for future webinar topics. Send your ideas to AskCTP@fda.hhs.gov.

Participate by Live Webcast / Phone

The link for the webinar and call-in information will be available prior to the webinar.

We recommend that you test your computer and network connections prior to the meeting via https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. No registration is required for these events. Web connections are limited and available on a first come basis.

Sign up to receive email updates about future webinars

Compliance Information on the CTP Website – Notify CTP of Potential Violations

- Anyone, including members of the public, can report instances of potential violations
- FDA evaluates each complaint and on a case by case basis and may conduct inspections or investigations to follow up on a complaint and gather evidence needed to pursue further action, when appropriate
- CTPCompliance@fda.hhs.gov
- 1-877-CTP 1373

Other Resources on the CTP Website –

Break the Chain of Tobacco Addiction

Retailer Education Campaign

- www.fda.gov/BreakTheChain --your one stop shop for FDA retailer specific information
- Publications Clearinghouse
 - Order free materials or download and print on the fly
- News & Quiz Widgets
- Content Syndication & Text Messages
- Spanish Web Content & Materials
- Connect With Us: Email Subscriptions, twitter, RSS feeds, Idea Forum

Other Resources on the CTP Website –

Break the Chain of Tobacco Addiction Retailer Education Campaign

Do You Sell TOBACCO Products?

Then you must comply with these federal laws:*

- Check photo ID of everyone appearing under age 27 who attempts to purchase cigarettes, cigarette tobacco, or smokeless tobacco.
- Only sell cigarettes, cigarette tobacco, and smokeless tobacco to anyone age 18 or older.¹
- Only sell cigarettes, cigarette tobacco, and smokeless tobacco in a direct, face-to-face exchange.⁴
- Do NOT give away free samples of cigarettes.
- Do NOT break open cigarette or smokeless tobacco packages to sell products in smaller amounts.
- Do NOT sell cigarette packages containing fewer than 20 cigarettes.
- Do NOT sell single cigarettes called "loosies."

Why Are These Laws Important?

These laws are designed to make regulated tobacco products less accessible and less attractive to youth. Every day nearly 3,450 kids try their first cigarette and this kid becomes a daily smoker. Many of these children will become addicted before they are old enough to understand the risks, and they may ultimately die of tobacco-related diseases. As a retailer, you play an important role in protecting children and adolescents by complying with the law.

For more information and free materials visit:
www.fda.gov/BreakTheChain
Phone: 1-877-287-1373 Email: AskCTP@fda.hhs.gov

* This is only a summary of federal laws. For the full list visit www.Fda.gov/BreakTheChain.
Readers must also follow state or local tobacco laws, even if they are more restrictive. For example, in some states the minimum age is 19.
1 The sale of cigarettes, cigarette tobacco, and smokeless tobacco through vending machines and self-service displays are allowed in adults-only facilities where no person younger than 18 is permitted to enter. Please note that tobacco product vending machines are banned in some states.

Dear Tobacco Retailer:

This flyer was updated to clarify that FDA currently regulates cigarette tobacco, smokeless tobacco, and roll-your-own tobacco.

Please share with:

ROMPE LA CADENA DE ADICCIÓN AL TABACO

No permitamos que los menores compren tabaco. Es la ley.

DON'T LET MINORS BUY TOBACCO

U.S. Food and Drug Administration New Federal Tobacco Laws
INFORMATION FOR RETAILERS

DON'T LET MINORS BUY TOBACCO

CO. IT'S THE LAW

BREAK THE CHAIN OF TOBACCO ADDICTION

PLEDGE

Pledge Map Spread the Pledge Connect About

Clint W. from Grover Beach, CA pledged to support responsible retailing!

POWERED BY Google

©2012 Google - Map data ©2012 Google, NEA

Pledged to support responsible retailing

Pledged to be a responsible retailer

TOTAL PLEDGES 739

Start Quiz

FDA Share Disclaimer Info

Free Print Materials and Information
available at
www.fda.gov/BreaktheChain

Bring our web content to your website!

<http://tools.fda.gov>

The screenshot shows the FDA Content Syndication - Home (Beta) page. At the top is the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". Below this is a navigation bar with links to Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. The main heading is "Content Syndication - Home (Beta)" with a "Sign in to Syndicate Content" button. A large blue banner reads "Free tobacco content to syndicate" with an illustration of a hand pointing to a computer screen. Below the banner, text explains that users can supplement their digital content with the latest in tobacco regulation, prevention, and cessation information from the FDA. It also states that once users choose the pages they want, they can register and use the code provided to bring the content to their site. The page is divided into two main sections: "Find Content" and "Learn More". The "Find Content" section has a "By Topic" list with links to "Learn about the Tobacco Control Act", "Protecting Youth From Tobacco", "Retailer Education", "State, Local, Tribal and Territorial Resources", "Tobacco Packaging and Advertising", "Guidance, Regulations and Compliance", and "Center for Tobacco Products News". It also includes a "Can't find what you are looking for?" section with links to "A-Z Topic List", "Find more content with Advanced Search", and "Request a Page to be Syndicated". The "Learn More" section has a "Technical Information" list with links to "API Documentation", "Usage Guidelines", "Request a Page to be Syndicated", and "Report a Problem with a Syndicated Page". At the bottom, there is a "By URL" section with a text input field and a "Search" button.

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

A to Z Index | Follow FDA | Subscribe to Emails

search

Home Food Drugs Medical Devices Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Radiation-Emitting Products Tobacco Products

Content Syndication - Home (Beta) [Sign in to Syndicate Content](#) REGISTER ? HELP + YOUR LIST

Free tobacco content to syndicate

Supplement your digital content and add the latest in tobacco regulation, prevention, and cessation information from the FDA. Our syndication hub allows easy access to a variety of tobacco-related content that you can use on your site for free.

Once you choose the pages you want, simply register and use the code provided to bring our content to your site. The automatic updates provide you with fresh content that requires minimal upkeep. [Learn more.](#)

Find Content

By Topic

- Learn about the Tobacco Control Act
- Protecting Youth From Tobacco
- Retailer Education
- State, Local, Tribal and Territorial Resources
- Tobacco Packaging and Advertising
- Guidance, Regulations and Compliance
- Center for Tobacco Products News

Can't find what you are looking for?

[A-Z Topic List](#)

[Find more content with Advanced Search](#)

[Request a Page to be Syndicated](#)

By URL

Enter a specific web page URL to see if the web page is available for syndication.

Most Popular Pages

- Frequently Asked Questions: Final Rule "Required Warnings for Cigarette Packages and Advertisements"
- FDA Tobacco Compliance Webinars
- Break the Chain of Tobacco Addiction
- Connect with Us
- Protecting the Public's Health: Infographic

Learn More

- What is Content Syndication?
- How Does Content Syndication Work?
- How Do I Find Content to Add to My Website?
- Frequently asked Questions
- Subscribe to Syndication Catalog Updates

Technical Information

- API Documentation
- Usage Guidelines
- Request a Page to be Syndicated
- Report a Problem with a Syndicated Page

Other Resources on the CTP Website –

CTP Site in Spanish (www.fda.gov/tabaco)

Departamento de Salud y Servicios Humanos de EE. UU.

FDA Administración de Alimentos y Medicamentos de los EE. UU.
Promoción y protección de su salud

Índice de la A a la Z | Siga a la FDA | Suscríbese a emails

BUSCAR

Inicio | Alimentos | Medicamentos | Aparatos | Vacunas/sangre/biológicos | Animal/veterinaria | Cosméticos | Prod. radioactivos | Prod. de tabaco

Productos de tabaco

Inicio Productos de tabaco

in English



Únase a los seminarios por Internet

FDA - Seminarios por Internet sobre tabaco y cumplimiento
Estos seminarios por Internet de la FDA están diseñados para informar y educar a los minoristas y pequeñas empresas sobre cumplimiento y tabaco.

1 2 3 4

Temas sobre productos de tabaco

Noticias y eventos (tabaco)
Notas de prensa, hojas de datos, informes de progreso y reuniones y conferencias

Información sobre normativas, cumplimiento y orientación (tabaco)
FDA y la regulación del tabaco: temas legales, normativos y de política en la Ley de Control del Tabaco y Prevención Familiar del Hábito de Fumar del 2009.

Etiquetas (tabaco)
La Ley de Control del Tabaco exige cambios en las etiquetas y los anuncios de algunos productos de tabaco.

Proteger del tabaco a los niños
La FDA trabaja para proteger la salud de los niños estadounidenses y reducir la carga de enfermedades y muertes causadas por el tabaco.

Recursos para usted (tabaco)
Para consumidores, industrias, minoristas, fabricantes, pequeñas empresas, profesionales de la salud y gobiernos territoriales, tribales, locales y estatales

Lo más popular

- Declaración de la FDA sobre el informe de la Academia Nacional de Medicina sobre la prevención del consumo de tabaco entre los jóvenes y adultos jóvenes
- Advertencias de salud por el cigarrillo
- Cursos para minoristas
- Infografía de la salud pública
- Cigarrillos electrónicos

Siga a la FDA

- Conéctese con nosotros
- Inscríbese: Programa piloto de textos con regulaciones sobre tabaco
- Inscríbese: emails con novedades sobre el tabaco
- Obtenga el widget de "Noticias útiles" del Centro de Productos de Tabaco
- Síganos en Twitter @FDATobacco

Other Resources on the CTP Website – Connect with Us

Get News and Information



Emails: Our email updates provide information specifically for retailers on sales, marketing, and distribution of tobacco products.



Widgets: Check out our widgets page to pledge to support responsible tobacco retailing, to get the latest news on FDA tobacco regulation, or to test your knowledge via our quiz widget. You can easily add FDA tobacco content to your website by embedding these widgets.



Text Messages: Sign up for the latest information on FDA tobacco regulations by texting BreakChain to 87000 from your mobile phone.

Help Spread the Word



RSS Feeds: Really Simple Syndication (RSS) provides information through subscription feeds about the latest tobacco news for retailers.



Content Syndication: FDA's syndicated content enables retailers to include information about tobacco regulations on their website.



Badges: Sharable [Break the Chain of Tobacco Addiction](#) badges provide an easy way for you to include a graphic on your website, blog or social network to help promote the Break the Chain of Tobacco Addiction campaign.



Buttons: [Protecting Kids from Tobacco](#) buttons are an easy way to include a graphic on your website, blog or social network to help promote the Break the Chain of Tobacco Addiction campaign.

Engage and Learn



Twitter: Get the latest updates from FDA Center for Tobacco Products by following us on Twitter [@FDATobacco](#).



Podcasts: Listen to our podcasts for information on what you need to know to comply with FDA tobacco regulations. You can also [subscribe](#) to our podcasts.



Videos: Watch video interviews with our text messaging mobile contest winners.

Tell Us Your Ideas



Idea Forum: Share your ideas about new tools and resources we could develop to improve tobacco retailer education.